510(K) Summary

I. SUBMITTER NAME & ADDRESSS: Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132
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OCT 0 3 2013

CONTACT PERSON: Kelly Anglin
Senior Regulatory Affairs Specialist

DATE PREPARED: October 02, 2013

II. PROPOSED PROPRIETARY TRADE NAME: MAGNIFUSE® II Bone Graft

DEVICE CLASSIFICATION NAME: Resorbable Calcium Salt Bone Void Filler
REGULATION NUMBER: 21 CFR 888.3045
CLASSIFICATION PRODUCT CODE: MQV, MBP
CLASS: II

III. IDENTIFICATION OF LEGALLY MARKETED DEVICES:

Table 1. LEGALLY MARKETED DEVICES

Device name	510(k) number	Substantial Equivalence date
MAGNIFUSE® Bone Graft	K123691	01/31/2013
MAGNIFUSE® II Bone Graft	K122513	03/06/2013

IV. DEVICE DESCRIPTION:

The implant in the subject device kit for MAGNIFUSE® II Bone Graft is assembled by the clinician at the time of the procedure using the supplied human bone allograft tissue matrix mixed 1:1 with autograft tissue. The mixture is packed into a polyglycolic acid (PGA) resorbable mesh bag with the supplied accessories included in the kit that consist of disposable plastic instruments spatula, funnel, and plunger. The resorbable mesh bag provides containment of the allograft/autograft mixture to prevent migration of the grafting material.

The allograft component of the predicate MAGNIFUSE® Bone Graft K123691 (S.E. 01/31/2013) and subject MAGNIFUSE® II Bone Graft is comprised of processed human cortical allograft bone particles. The particles consist of demineralized bone matrix (DBM) in a fiber form as an osteoinductive component combined with non-demineralized cortical fibers as the osteoconductive component. The allograft bone is derived from human tissue recovered in the U.S. by FDA registered tissue bank establishments. The tissue is recovered from a cadaveric donor using aseptic surgical techniques and has been microbiologically tested during recovery. Incoming donor bone tissue is subjected to various screening and testing requirements before it is released for processing in accordance with FDA requirements for donor suitability/eligibility. The final product in packaged form is tested for sterility according to the procedures in the current U.S. Pharmacopoeia USP standard <71>.

The purpose of this 510(k) application is to modify the current composition, the ratio and processing technique of the allograft component contained in the subject MAGNIFUSE® II Bone Graft device to improve donor utilization. These proposed modifications to the allograft component are identical to the predicate MAGNIFUSE® Bone Graft K123691 (S.E. 01/31/2013). Refer to **Table 2** below for the summary of the technological characteristics related to the allograft component contained in the subject device. All other aspects of the subject MAGNIFUSE® II Bone Graft device are identical to the

predicate MAGNIFUSE® II Bone Graft K122513 (S.E. 03/06/2013) device with the exception of the changes to the allograft component mentioned above. Refer to **Table 3** below for the summary of the technological characteristics. The detailed descriptions are outlined in the substantial equivalence discussion section of this 510(k).

V. INDICATIONS FOR USE:

MAGNIFUSE® II Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. MAGNIFUSE® II Bone Graft is resorbed/remodeled and replaced by host bone during the healing process.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

Table 2: Summary of the technological Characteristics Allograft component

Comparison Feature	**Subject MAGNIFUSE® II Bone Graft**	**Predicate MAGNIFUSE® Bone Graft (K123691 S.E. 01/31/2013)**
Allograft component • Demineralized Bone Matrix (DBM) in fiber form • Non-demineralized fibers	Identical	K123691 S.E. 01/31/2013
Allograft Ratio	Identical	K123691 S.E. 01/31/2013
Processing Method of DBM fibers	Identical	K123691 S.E. 01/31/2013

Table 3: Summary of the technological Characteristics		
Comparison Feature	**Subject MAGNIFUSE® II Bone Graft**	**Predicate MAGNIFUSE® II Bone Graft (K122513 S.E. 03/06/2013)**
Indication for Use	Identical	K122513 S.E. 03/06/2013
Fundamental Scientific Technology • Operating Principle • Mechanism of Action	Identical	K122513 S.E. 03/06/2013
Basic Design	Identical	K122513 S.E. 03/06/2013
Performance	Identical	K122513 S.E. 03/06/2013
Sterilization	Identical	K122513 S.E. 03/06/2013
Shelf-Life	Identical	K122513 S.E. 03/06/2013
Packaging	Identical	K122513 S.E. 03/06/2013
Use of rigid fixation	Identical	K122513 S.E. 03/06/2013
Safety and Effectiveness profile	Identical	K122513 S.E. 03/06/2013
PGA Mesh bag Closure Mechanism	Identical	K122513 S.E. 03/06/2013

VII. DISCUSSION OF NON-CLINICAL TESTING:

Non-clinical testing was performed in accordance with FDA Recognized Consensus Standards and FDA Guidelines, where applicable. A rabbit posterolateral lumbar spinal fusion study was conducted to evaluate the bone formation capabilities of the subject device related to the proposed allograft formulation change from cortical bone chips/fibers to cortical bone fiber/fiber formulation. The manual palpation and radiographic results for the subject device demonstrates equivalency to the predicate MAGNIFUSE® Bone Graft device K123691 (S.E. 01/31/2013). The complete test report and summary can be found in the **Animal Performance Testing** section of this application.

The allograft component of the subject device will be processed via a proprietary processing method that has been shown to consistently produce demineralized bone matrix that is osteoinductive in an athymic rat assay. Like the predicate MAGNIFUSE® Bone Graft device K123691 (S.E. 01/31/2013), the tissue processing of the subject will be confirmed via ongoing testing of finished product for osteoinductivity in this validated athymic rat assay utilizing a five-point linear scale (0, 1, 2, 3, 4) to score bone formation at 28 days post implantation*. Bone formation in the athymic rat surrogate assay should not be interpreted as a predictor of clinical performance.

* Edwards etal; Osteoinduction of Human Demineralized Bone: Characterization in a Rat Model. Clinical Orthopaedics, December 1998, Vol 357.

Viral inactivation of the demineralized fibers in the subject MAGNIFUSE® II Bone Graft device includes proprietary processing steps of demineralizing acid soaks followed by alcohol soaks and dehydration. Viral inactivation of the non-demineralized cortical fibers in the subject device is provided by alcohol soaks and by dehydration using supercritical CO_2. These processing steps that have been shown and validated to inactivate viruses including: HIV-1; hepatitis B virus (duck hepatitis virus as model); hepatitis C virus (bovine diarrhea virus as model), CMV; and Polio virus. These processes further reduce the risk of disease transmission via the use of this product beyond the protection provided by donor testing and screening procedures.

VIII. CONCLUSION:

Documentation provided in this submission demonstrates that the subject device is substantially equivalent to the previously cleared MAGNIFUSE® Bone Graft device K123691 (S.E. 01/31/2013) for the allograft component and MAGNIFUSE® II Bone Graft K122513 (S.E. 03/06/2013) for all other aspects of the subject device.

The subject device is substantially equivalent to predicate MAGNIFUSE® II Bone Graft in several categories including: indication, material components, sterility, shelf-life, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Medtronic Sofamor Danek USA, Incorporated
Ms. Kelly Anglin
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K131673
Trade/Device Name: MAGNIFUSE® II Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: August 14, 2013
Received: August 16, 2013

Dear Ms. Anglin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131673

510(k) Number (if known):

Device Name: MAGNIFUSE® II Bone Graft

INDICATIONS FOR USE:

MAGNIFUSE® II Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. MAGNIFUSE® II Bone Graft is resorbed/remodeled and replaced by host bone during the healing process.

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131673